Message

From: Michelle Deveau [michelle.deveau@hc-sc.gc.ca]
Sent: 7/29/2015 9:35:35 PM
To: Donohue, Joyce [Donohue.Joyce@epa.gov]
CC: Richard Carrier [richard.carrier@hc-sc.gc.ca]
Subject: Peer review of Health Canada's draft Guideline Technical Documents for PFOS and PFOA
Attachments: PFOS GTD 2015-07 (for consultation) en.doc; PFOA GTD 2015-07 (for consultation).doc; Summit report FINAL.pdf; Summary of BMD modeling for endpoints in assessments.xlsx; Animal-to-human extrapolation calculations.xlsx; MOA Analysis Tables - PFOS.docx; MOA Analysis Tables - PFOA.docx

Hello Joyce,

Thank you for agreeing to be a peer reviewer for the draft Guideline Technical Documents for the Guidelines for Canadian Drinking Water Quality for PFOS and PFOA. Based on your expertise and risk assessment experiences related to these compounds, we are looking forward to your insight on our draft documents. Below you will find some guidance and information related to your review.

Suggested deadline
In your previous discussions with Richard Carrier, a rough deadline of the end of August was given to you. However, we have recently become aware of new challenges in our scientific editing contracts, which will require longer time periods for the editing process. If your schedule allows you to complete the review earlier than the previously discussed date, this would be greatly appreciated. Moreover, if you are able to provide partial reviews early (e.g. if you have finished the review for one compound earlier than the other, or if you could provide your comments specific to Section 10, particularly if you're recommending changes to the health-based values), this would be greatly appreciated.

Peer review charge questions
Suggested questions to guide the review are listed below; however, please feel free to make comments on any additional topics that you see fit.

General questions:

- Was the document clear, transparent, and well written?
- Are you aware of any omitted studies that, if included, could affect the derivation of the Health-Based Values?

Selection of points of departure (PODs):

- Do you believe the correct PODs were selected for each compound? If not, please suggest your recommended POD(s), along with support for your selection. Please also suggest any additional PODs that you think should be considered for inclusion in the dose–response analyses.
- Was the discussion sufficient to support the exclusion of immunological (PFOS) or developmental (PFOA) effects?
- Do you believe there is sufficient support provided for considering PFOA-induced liver weight increases and hepatocellular hypertrophy as PODs? If not, please provide additional data or guidance references that could be used to further support the decision, or identify whether you believe these effects to be adaptive.
    - If you consider the liver effects to be adaptive, please identify whether you believe cholesterol changes would be an appropriate POD for a health-based value; if you do not, please suggest an alternative POD.

Animal-to-human extrapolation:

- Is the reasoning for using the PBPK model-derived CSAF values over other animal-to-human approaches sufficiently supported? If not, what further details would you suggest to include to strengthen the justification?
- Do you agree that this is the appropriate approach for the animal-to-human extrapolation? If not, please provide support for your preferred animal-to-human extrapolation approach.
- Is the reasoning for excluding the full use of the PBPK model to derive points of departure sufficiently supported?

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Other questions:

- Are the correct uncertainty factors used? Are there any UFs that were not used that should be considered, or are there any UFs that were used that should be excluded, decreased, or increased?
- Do you agree with the conclusions of the mode of action analysis?

Attached documents
The following documents have been attached to this email:

For your review:

- Draft Guideline Technical Document for PFOS
- Draft Guideline Technical Document for PFOA

As supplemental materials:

- Summit Toxicology report on animal-to-human extrapolation approaches
- Excel spreadsheet with benchmark dose modelling outputs for relevant endpoints
- Excel spreadsheet with calculations of the health-based values
- Mode of action analysis tables

If you require any further supplemental materials or articles referenced in the documents, please do not hesitate to contact Michelle Deveau.

Focus of the review
We realize these documents are long, and that you might not have sufficient time to perform a thorough review of both documents. Our suggested areas for the focus of the document, from highest to lowest priority, are as follows:
1) Section 10 - Classification and Assessment (PFOS: pp. 41-52; PFOA: pp. 43-56)
2) Section 9.3 - Mode of action (PFOS: pp. 38-41; PFOA: pp. 40-43)
3) Sections 9.1 - Effects in humans (PFOS: pp. 16-23; PFOA: pp. 16-26) and 9.2 - Effects on experimental animals (PFOS: pp. 23-38 ; PFOA: pp. 26-40)
4) Section 8 - Kinetics and metabolism (Both documents: pp. 11-16)
5) Section 4 - Identity, use and sources in the environment (Both documents: pp. 4-7) and 5 - Exposure (Both documents: pp. 7-11)

Please note that this document has not yet undergone technical editing, so please do not worry about making this a focus of your revision (unless you identify an error that changes the scientific meaning of anything in the document).

If you have any questions or concerns, please do not hesitate to contact me.

Thanks,
Michelle

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